# Kids Have Problem With Medical Product?

Consumers can play a critical role in helping the Food and Drug Administration (FDA) assure children's access to safe medical products.

**Does your child have a problem with a medical product? Letting us know could help all children.**

Reporting to FDA such "adverse events" as unexpected, serious side effects, accidental exposure, and product quality issues can prompt the agency to act—and it can also bring new pediatric safety information to light.

Reports submitted to FDA make a difference, says Dianne Murphy, M.D., director of FDA's Office of Pediatric Therapeutics (OPT), which focuses on safety, scientific and ethical issues that arise in pediatric clinical trials (tests of new medical products that are required before the products may be approved) or after products are approved for use in children. "Even a single well-documented report can lead to additional research and analysis that might result in a label change or other FDA action."

Why is this especially important for medical products involving children?

"Most pediatric clinical trials involve a relatively small number of patients," says Murphy, and problems might not be detected until the products are in widespread use. And a drug or device might be studied in one pediatric age group, but prescribed and used in another age group in which it has not been studied, she says.

"Of the millions of adverse event reports submitted to FDA, only a small percent are for children," says Jo Wyeth, Pharm.D., a safety evaluator with FDA's Office of Surveillance and Epidemiology (OSE), an office that tracks such reports. In 2012, FDA received nearly 900,000 adverse event and medication error reports, but only 5 percent were associated with children under 18 years of age.

## Example of Reporting Benefits

In 2007, the agency began receiving consumer accounts of serious side effects in children who were acciden-

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tally exposed to prescription topical testosterone gel products through contact with the skin of an adult male in their household who was using these products.

This information triggered an FDA investigation that resulted in stronger warning labels to alert the public. FDA also worked with testosterone gel product manufacturers to create potentially safer versions and to identify places on the body where the gel could be applied so that it is less likely to come into contact with children.

"Those reports from consumers made a big difference," Wyeth says. "It was extremely rewarding to work with those families who suspected that something might be going wrong and contacted FDA to investigate the situation. We want to prevent these harmful situations from happening to others and ensure medical products are safe for everyone to use."

## What to Include

Many adverse event reports do not include relevant information, such as the patient's age, which can delay the identification of serious problems in children. "The quality of reports is important," says OSE director Gerald Dal Pan, M.D., M.H.S. "Document what is happening as much as possible. FDA needs the same kind of information as your health care provider to assess a potential problem with a medication."

Consumers don't have to prove that a medication or device caused the problem. "What I have found to be most helpful in reports from consumers is a clear statement about the event, followed by a more detailed description of what happened," says Wyeth. FDA also recommends including information about:

- Product name, type, dose, and how it was given (or administered);
- How long the product was used;
- Age of the child;
- Other medications or medical conditions present at the time of event;
- Outcome (such as what happened to the child if the medical product was stopped); and
- Contact information for the person submitting the report and for the child's health care professional.

Consumers often have the most details about what they are experiencing and should contact their health care provider for medical care, and then report the problem to the FDA.

## What Happens to the Report

Each report is stored in a database monitored by FDA staff, who evaluate the reports, consult with medical staff and the manufacturer, and determine if more study is needed. There is a wide range of ways for FDA to communicate new safety information to the public, including warnings in the product label, patient monitoring recommendations, dosage adjustments for certain patients, medication guide updates, special programs like registries, and product withdrawal. (Medication guides are paper handouts given with certain medications by the pharmacist.)

FDA's Pediatric Advisory Committee, a group of outside experts, meets two to three times a year to review adverse events for products recently labeled for use in children. Reviews for 215 products have been presented to the committee through September 2012. OPT maintains a Safety Reporting Page with information on products that the advisory committee has evaluated:

*www.fda.gov/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/ucm123229.htm*

## How to submit a report

Consumers should report serious side effects or product quality problems to FDA's MedWatch: The FDA Safety Information and Adverse Event Reporting program.

- Online: MedWatch Reporting *www.fda.gov/Safety/MedWatch/HowToReport/default.htm*
- Regular Mail: use postage-paid FDA form 3500 and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Phone: (800) FDA-1088

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